IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ROCK HILL DIVISION

Clayton Carnes and Linda Carnes (h/w), Plaintiffs,	Civil Action No. 0:13-591-CMC
vs.	**JOINT RULE 26(f) REPORT AND DISCOVERY PLAN**
ELI LILLY AND COMPANY, an Indiana Corporation,	
Defendant.	

Pursuant to Rule 26(f) of the Federal Rules of Civil Procedures and Local Civil Rule 26.03 DSC, the parties jointly submit the following:

The parties, having consulted pursuant to Rule 26(f), Fed. R. Civ. P., hereby report as follows (check one below):

☐ We agree that the schedule set forth in the Conference and Scheduling Order filed is appropriate for this case. **The parties' proposed discovery plan as required by Fed. R. Civ. P. Rule 26(f) and the information required by Local Civil Rule 26.03 are attached.**

☐ We agree that the schedule set forth in the Conference and Scheduling Order filed requires modification as set forth in the proposed Consent Amended Scheduling Order which will be e-mailed to chambers as required (use format of the Court's standard scheduling order). **The parties' proposed discovery plan as required by Fed. R. Civ. P. Rule 26(f) and the information required by Local Civil Rule 26.03 are attached.**

☒ We are unable, after consultation, to agree on a schedule for this case. We, therefore, request a scheduling conference with the Court. **The parties' proposed discovery plan as required by 26(f) Fed. R. Civ. P., with disagreements noted, and the information required by Local Civil Rule 26.03 are attached.**

JOINT DISCOVERY PLAN

(A) What changes should be made in the timing, form, or requirement for disclosures under Rule 26(a), including a statement of when initial disclosures were made or will be made.

RESPONSE: The parties agree that Rule 26(a) disclosures should be made on May 15, 2013, as set forth in the current scheduling order applicable to this case.

(B) The subjects on which discovery may be needed, when discovery should be completed and whether discovery should be conducted in phases or be limited to or focused on particular issues.

RESPONSE: Discovery will be conducted on the allegations in the Complaint and the defenses in the Answer, including discovery on the Plaintiff's claimed injuries, medical conditions, and alleged damages, Defendant's liability, and general and case-specific causation. Given the complex nature of this pharmaceutical products liability case, the parties are in agreement that the deadlines in the Court's current proposed scheduling order should be extended and are in agreement on the length of those extensions. Specifically, the parties agree that discovery should be completed by May 2, 2014, and that the trial of this case should not occur before October 13, 2014.

However, the Defendant proposes a two-phased discovery scheme. The first phase would include a "Core Discovery Period" focused on (1) the production of a targeted universe of documents related to Cymbalta's development and labeling and the medical records documenting Plaintiff's Cymbalta treatment and treatment of any side effects allegedly arising from Plaintiff's discontinuation of Cymbalta and (2) the deposition of Plaintiff's prescribing

physician. The second, "Non-Core Discovery" phase would encompass any remaining depositions and document production. Defendant's proposed schedule is set forth at **Exhibit A**.

The parties' respective positions are set forth below.

PLAINTIFFS' SUGGESTED DISCOVERY PROTOCOL:

This matter is one of several cases currently pending in the federal courts and alleging "withdrawal" injuries from the use and discontinuation of Defendant's prescription antidepressant drug, Cymbalta. Undersigned Plaintiff's counsel anticipates that these cases eventually will be consolidated into a Multidistrict Litigation (MDL). Plaintiffs with pending federal actions arising from Cymbalta withdrawal injuries expect to petition the Judicial Panel on Multidistrict Litigation for an MDL in the coming weeks or months.

As in any pharmaceutical products liability case, Plaintiffs expect generic discovery – especially discovery relating to Defendant's liability and expert discovery on general causation – to be lengthy and extensive. Plaintiffs anticipate such generic discovery will be overseen by an eventual MDL Court. For that reason, Plaintiffs submit to this Court that the dichotomy and categories laid out in Defendants' suggested "tiered" discovery plan are premature and unnecessary at this time. Instead, Plaintiffs request that this Court simply set a final overall discovery deadline of May 2, 2014 in this matter, pending and subject to the commencement of an MDL. In the event an MDL is convened and this case is transferred to that MDL, the parties would revisit an appropriate case-specific discovery schedule with this Court when and if the case is remanded. If for some reason an MDL is not convened, the parties can easily meet and confer again to discuss whether the Court's scheduling order should address more detailed discovery categories or deadlines.

DEFENDANT'S ARGUMENT FOR TIERED DISCOVERY:

This Court should adopt Defendant's proposed discovery schedule because it would allow a threshold dispositive issue to be addressed at an early stage of the litigation, thus potentially saving both the Court and the parties significant time and expense in discovery costs. Specifically, Defendant proposes that the Court direct that the parties promptly take the deposition of Dr. Trey Knight, the physician who prescribed Cymbalta® to Plaintiff Clayton Carnes, Compl. ¶32, to determine his testimony on two questions: (1) whether he was misled or failed to understand the risks arising from the discontinuation of Cymbalta® when he prescribed the medicine to Mr. Carnes, and (2) whether a different warning of the sort apparently sought by Mr. Carnes would have changed Dr. Knight's decision to prescribe Cymbalta® to Mr. Carnes. Unless Dr. Knight answers yes to both of these questions, Mr. Carnes' lawsuit cannot proceed. Plaintiffs' proposal to seek consolidation of this suit with other pending matters at some unspecified point in the future should not preclude this Court from establishing a focused discovery schedule that would facilitate efficient resolution of these core issues.

Plaintiffs raise product liability claims seeking monetary relief for injuries allegedly resulting from Mr. Carnes' treatment with Cymbalta® (duloxetine). Cymbalta® is an FDA-approved prescription medicine manufactured by Defendant to treat severe depression, anxiety, and pain disorders, including fibromyalgia. Each of Plaintiffs' claims hinges on a single premise: that Defendant failed to warn adequately of possible side effects related to discontinuing Cymbalta® treatment.[1] These adverse effects are sometimes referred to as "discontinuation-emergent adverse events" ("DEAEs").

[1] In South Carolina product liability cases, "[r]egardless of the particular theory under which the plaintiff proceeds, he must establish . . . 'that the injury occurred because the product was in a defective condition unreasonably dangerous to the user.'" *Sauls v. Wyeth Pharms. Inc.*, 846 F.

At the time Mr. Carnes took Cymbalta®, the medicine's warning to physicians provided the following extensive discussion about the risk of DEAEs:

> 5 WARNINGS AND PRECAUTIONS
>
> . . . .
>
> 5.6 Discontinuation of Treatment with Cymbalta
>
> Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at 1% or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, paresthesia, fatigue, vomiting, irritability, insomnia, diarrhea, anxiety, and hyperhidrosis.
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> During marketing of other SSRIs and SNRIs (serotonin and noreprinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.
>
> Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate [*see Dosage and Administration (2.4)*].

Cymbalta Physician Packet Insert (March 2011), Exhibit B.

Because Cymbalta® is a prescription medicine, the learned intermediary doctrine provides that "the manufacturer's duty to warn extends only to the prescribing physician, who

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Supp. 2d 499, 502 (D.S.C. 2012) (citation omitted). Prescription drugs "generally are neither defective nor unreasonably dangerous as long as they are accompanied by proper directions and warning." *Id.* (internal quotation marks omitted) (citation omitted).

then assumes responsibility for advising the individual patient of risks associated with the drug or device." *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (applying South Carolina law); *see also Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) (concluding that the South Carolina Supreme Court would adopt the learned intermediary doctrine); *Madison v. American Home Products Corp.*, 595 S.E.2d 493, 455 (S.C. 2004) ("[S]trict liability is inconsistent with the learned intermediary doctrine, which places the duty to warn on the prescribing physicians . . . .") (internal quotation marks omitted) (citation omitted). Thus, Plaintiffs have a threshold evidentiary burden of demonstrating that the prescribing doctor was misled or failed to understand the risk of DEAEs with Cymbalta®.

In addition to coming forward with evidence that Cymbalta®'s extensive DEAE warning was not adequate to inform the medical community about the risk of DEAEs with the use of Cymbalta®, Plaintiffs must also come forward with evidence that any alleged inadequacy was the ***proximate cause*** of Mr. Carnes injuries. To establish proximate cause, Plaintiffs must make two showings: **First**, they must demonstrate that Dr. Knight did not have independent knowledge of the potential risks of discontinuation events associated with Cymbalta®. *See Odom*, 979 F.2d at 1003 (agreeing with the "district court's conclusion that [plaintiff's physician] would have prescribed the [medical device] no matter how carefully [the manufacturer] refined the phrasing of its warning" where the physician "testified at length about his independent knowledge of the risk of [the alleged injury]"). Here, that burden will be difficult to meet in light of the general medical understanding that the discontinuation of antidepressant medications can in fact lead to these types of DEAEs.[2] If Dr. Knight testifies that

[2] Here, the very article upon which Plaintiffs premise their complaint describes the widespread medical understanding that antidepressants like Cymbalta can lead to these types of DEAEs. *See* David G. Perahia et al., Symptoms following abrupt discontinuation of duloxetine treatment in

he understood the risks of DEAEs when he prescribed Cymbalta® to Mr. Carnes, the lawsuit is over.

Second, Plaintiffs must also show that, had Dr. Knight been given what they allege would be an "adequate" warning, Dr. Knight would have decided not to prescribe Cymbalta® to Mr. Carnes. *See Odom*, 979 F.2d at 1003 (characterizing "the sole issue" in the failure-to-warn case "whether an adequate warning" about the alleged injury "would have deterred" the physician from making the same prescribing decision). In other words, summary judgment is proper where "'plaintiff has presented nothing to establish a causative link between the alleged failure to warn and the decision by the plaintiff's physician to prescribe the product.'" *Id.* at 1002; *see also Sauls*, 864 F. Supp. 2d at 502 (Plaintiff "must 'demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff.'") (citing *Odom*, 979 F.2d at 1003). Here, if Dr. Knight testifies that a different warning would not have changed his prescribing decision, Plaintiffs' claims likewise cannot proceed.

The parties can answer these threshold questions with targeted discovery, and setting up a procedure that allows the Court to resolve these issues before significant discovery serves the interests of judicial economy and the efficient resolution of disputes. Accordingly, Defendant respectfully requests that the Court adopt its proposed schedule.[3]

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patients with major depressive disorder, 89 J. of Affective Disorders 207, 207 (2005) ("2005 JAD Article"), Exhibit C ("Discontinuation symptoms are common following antidepressant treatment.").

[3] Defendant anticipates that Plaintiffs will argue that they must have discovery from Defendant before Dr. Knight's deposition takes place. While Defendant disagrees that discovery is actually necessary, Defendant's schedule envisions the prompt production of the new drug application ("NDA") and investigational new drug ("IND") application files for Cymbalta, amounting to approximately 1.6 million pages of documents. The NDA and IND files reflect the entire regulatory files for the medicine, including reports of pre-clinical (animal) studies and clinical

(C) Any issues about disclosures or discovery of electronically stored information, including the form or forms in which it should proceed.

RESPONSE:

PLAINTIFFS' POSITION: As explained above, Plaintiffs expect that this matter eventually will be consolidated with other similar Cymbalta withdrawal cases in an MDL. While Plaintiffs agree in principle that a confidentiality order may be necessary, they submit that the MDL would be the appropriate forum in which to address such an order.

DEFENDANT'S POSITION: At this time, there do not appear to be any special issues related to the disclosure or discovery of electronically stored information. The parties reserve the right to identify issues that may arise related to disclosures or discovery of electronically stored information.

(D) Any issues about claims of privilege or of protection as trial-preparation materials, including – if the parties agree on a procedure to assert these claims after production – whether to ask the court to include their agreement in an order.

RESPONSE: The Parties agree that an appropriate confidentiality order should be entered by the Court. The Parties will meet and confer regarding an order and provide a proposed order for the Court.

(human) studies, the product's labeling, the adverse event reporting, and the correspondence files reflecting the interactions with the FDA. *See, e.g.*, *Upjohn Co. v. Dalton*, 829 S.W.2d 83, 84-85 (Mo. Ct. App. 1992) (plaintiff alleging prescription drug Halcion caused decedent's suicide should begin by reviewing the 400,000 page NDA). Given that Plaintiffs' claim is premised on Defendant's own publicly-available study, it is difficult to envision how this large amount of additional information would not more than satisfy any legitimate demand of discovery from Defendant.

(E) What changes should be made in the limitation on discovery imposed under these rules or by local rule, and what other limitations should be imposed.

RESPONSE: At this time, the Parties are not aware of any changes that should be made in the limitations on discovery imposed under the applicable civil rules or any other limitations that should be imposed.

(F) Any other orders that the court should issue under Fed. R. Civ. P. 26(c) or under Fed. R. Civ. P. 16(b) and (c).

ANSWER: None identified at this time.

LOCAL RULE 26.03 DISCLOSURES

(1) A short statement of the facts of the case.

ANSWER: Plaintiffs have brought this action alleging that Plaintiff Clayton Carnes ingested the prescription medication Cymbalta®, which caused him personal injuries and damages, including discontinuation symptoms.

Defendant is the responsible U.S. entity for the development, manufacture of Cymbalta®, which is an FDA-approved prescription medication indicated for Major Depressive Disorder ("MDD"), Generalized Anxiety Disorder ("GAD"), and fibromyalgia. Defendant asserts that there is no factual basis for Plaintiffs' allegations, and has denied the material allegations of Plaintiffs' Complaint and asserted numerous defenses.

(2) The names of fact witnesses likely to be called by the party and a brief summary of their expected testimony.

PLAINTIFFS' RESPONSE:

Discovery has not yet commenced, and accordingly, a complete fact witness list is not yet possible. At this stage, Plaintiffs anticipate the following witnesses or categories of witnesses but reserve the right to supplement this list at the completion of discovery:

1. Plaintiff Clayton Carnes
2. Plaintiff Linda Carnes
3. Plaintiff's healthcare providers, including prescribing physician Dr. Trey Knight
4. Any and all employees of Defendant Eli Lilly and Co. with knowledge of Cymbalta and/or the allegations in Plaintiffs' Complaint, including but not limited to the following categories:
    a. The study, testing, and/or research of Cymbalta, pre- and post-marketing;
    b. Regulatory affairs relating to Cymbalta, including communications between Defendant and the Food and Drug Administration (FDA);
    c. Product labeling, warnings, precautions, and/or communications to healthcare providers relating to Cymbalta;
    d. Adverse event reporting, post-marketing surveillance, and/or pharmacovigilance relating to Cymbalta;
    e. Sales and marketing relating to Cymbalta;
    f. Defendants' sales representatives or detail persons who called on Plaintiff's healthcare providers; and
    g. Revenues and/or profits derived from Cymbalta and company net worth

DEFENDANT'S RESPONSE:

Defendant has not yet begun the discovery process in this case and, as such, is not in a position to provide a complete factual witness list. Additional witnesses may arise after information is received.

1. Clayton Carnes
   Mr. Carnes is a Plaintiff in this action.

2. Linda Carnes
   Ms. Carnes is a Plaintiff in this action.

3. Dr. Trey Knight
   Dr. Knight was a treating physician of Plaintiff Clayton Carnes.

4. Any and all of Plaintiff Clayton Carnes' other healthcare providers or professionals.

5. Any and all individuals with knowledge of Plaintiff's health history.

6. Custodian of records or other qualified individuals as necessary to establish evidentiary foundations, including but not limited to, custodians of records or other qualified individuals for Plaintiff's healthcare providers.

7. Any and all individuals identified by Plaintiffs or in documents produced by Plaintiffs in their initial disclosures or other discovery responses.

8. Company witnesses: To date, Defendant has identified the following individuals with knowledge or information regarding the design, testing, labeling and regulatory aspects of the product at issue:

   a. Sharon Hoog, M.D.
      Eli Lilly and Company

   b. David Perahia, M.D.
      Eli Lilly and Company

Defendant reserve the right to supplement this list as discovery proceeds.

(3) The names and subject matter of expert witnesses (if no witnesses have been identified, the subject matter and field of expertise should be given as to experts likely to be offered).

RESPONSE: Neither Plaintiffs nor Defendant have retained any expert witnesses at this time. The parties reserve the right to identify expert witnesses in accordance with the deadlines provided in the scheduling order and any subsequent amendments.

At this early stage, Plaintiffs anticipate identifying experts in the following areas: (1) Defendants' liability arising from failure to properly and adequately test, study, and warn about the risks of Cymbalta; (2) general causation (*i.e.*, that Cymbalta can cause withdrawal injuries); (3) specific causation (*i.e.*, that Cymbalta was the cause of Plaintiff's withdrawal injuries); (4) marketing; and (5) Defendant's revenue and profits from Cymbalta and company net worth. Plaintiffs reserve the right to supplement this general list upon completion of discovery.

Defendant presently anticipates identifying experts in the following categories: (1) FDA regulatory affairs and labeling and (2) pain management (including, e.g., rheumatology, neurology, orthopedics, and psychology) and the treatment of fibromyalgia and otherwise reserves the right to supplement this list as discovery proceeds.

(4) A summary of the claims or defenses with statutory and/or case citations supporting the same.

SUMMARY OF PLAINTIFFS' CLAIMS

Plaintiff Clayton Carnes was injured by his ingestion of Cymbalta, which reached him in essentially the same condition as when it left Defendant's hands and which was in an unreasonably dangerous condition insofar as it was defectively designed and inadequately labeled. *See Rife v. Hitachi Constr. Mach. Co., Ltd.*, 609 S.E.2d 565 (S.C. Ct. App. 2005). As stated in Plaintiffs' complaint, Defendant is liable in negligence, strict liability, and breach of warranty for failing to exercise reasonable care in the design and labeling of Cymbalta, failing to adequately warn about the risks of Cymbalta, and failing to comply with the warranties it created

relating to the use and efficacy of Cymbalta. *See* S.C. Code Ann. § 15-73-10, *et seq.*; §§ 36-2-313 to -314; and *Anderson v. Green Bull, Inc.*, 471 S.E.2d 708, 710 (S.C. Ct. App. 1996).

Plaintiffs also make claims for negligent misrepresentation and fraud arising from Defendants' negligent and knowingly misleading communications to healthcare providers and consumers concerning the safety and efficacy of Cymbalta. *See McLaughlin v. Williams*, 665 S.E.2d 667 (S.C. Ct. App. 2008).

Plaintiffs' damages include compensatory damages for personal injuries and loss of consortium. *See Preer v. Mims*, 476 S.E.2d 472 (S.C. 1996). Additionally, Defendant's conduct was willful, wanton, and in reckless disregard to Plaintiff's safety and rights, warranting an imposition of punitive damages. *See Rife*, 609 S.E.2d at 569.

SUMMARY OF DEFENDANT'S CLAIMS

(1) General denial. Defendant denies all allegations not specifically explained or admitted in their Answer.

(2) Failure to state a claim. The Complaint fails to state a claim or cause of action upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6).

(3) Comparative and/or Contributory Fault. Any amount that Plaintiffs claim as compensatory damages, if the claims for such amounts are not entirely barred, must be diminished proportionately by the fault of Plaintiffs, and the fault of all others who caused or contributed to cause the harm. S.C. Code § 15-38-10 *et seq.*, *Clark v. Cantrell*, 529 S.E.2d 528 (S.C. 2000); *Hurd v. Williamsburg County*, 579 S.E.2d 136 (S.C. Ct. App. 2003); *Nelson v. Concrete Supply Co.*, 399 S.E.2d 783, 784 (S.C. 1991).

(4) Conduct of Other Parties. The claims set forth in the Complaint are barred because any injury or heightened risk was caused, in whole or in part, by the conduct of one or

more persons or entities over whom the Defendant exercised no control and with whom the Defendant had no legal relationship or responsibility. *Johnson v. Pittman*, 380 S.E.2d 850 (S.C. Ct. App. 1989); *Collins & Sons Fine Jewelry, Inc. v. Carolina Safety Sys.*, 371 S.E.2d 539 (S.C. Ct. App. 1988).

(5) Independent, Intervening, or Superseding Cause. The claims set forth in the Complaint are barred because any injury or heightened risk was caused, in whole or in part, by an intervening cause or causes sufficient to break the causal nexus to any alleged act or omission by the Defendant. *See Johnston v. Pittman*, 380 S.E.2d 850 (S.C. Ct. App. 1989); *Collins & Sons Fine Jewelry, Inc. v. Carolina Safety Sys. Inc.*, 371 S.E.2d 539 (S.C. Ct. App. 1988).

(6) Failure to Mitigate Damages: Damages recoverable by Plaintiffs, if any, must be reduced by any amount of damages legally caused by the Plaintiffs' failure to mitigate such damages in whole or in part. *See generally Brannon v. Knauss*, 320 S.E.2d 470 (S.C. 1984); *Baril v. Aiken Regional Med. Ctrs.*, 573 S.E.2d 830 (S.C. Ct. App. 2002).

(7) Learned Intermediary Doctrine. Defendant provided complete and adequate warnings to Plaintiff's physicians; therefore, any claims by Plaintiffs for inadequate warnings are barred by the learned intermediary doctrine. In addition, where a physician independently knows of the alleged medical risk, the Defendant cannot be said to have caused the alleged injury. *Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001 (4th Cir. 1992); *Brooks v. Medtronic, Inc*., 750 F.2d 1227 (4th Cir. 1984).

(8) Causation. There exists no proximate causation between any alleged act, omission or breach of duty by Defendant and Plaintiffs' alleged damages, injuries, and/or losses, if any, which were the result of conduct of persons or entities other than Defendant. *Odom v. GC Searle & Co.*, 979 F.2d 1001 (4th Cir. 1992).

(9) Misuse. Any injuries that Plaintiffs sustained may have been due to and proximately caused by Plaintiffs' unforeseeable abuse, misuse, or improper use of the product. *Small v. Pioneer Machinery, Inc.*, 494 S.E.2d 835 (S.C. Ct. App. 1997); *see also Bragg v. Hi-Ranger*, 462 S.E.2d 321, 328 (S.C. Ct. App. 1995).

(10) Statute of Limitations. The causes of action alleged in Plaintiffs' Complaint are barred by the applicable statute of limitations.

(11) State of the Art. Plaintiffs cannot recover under the Complaint because the product was in conformity with the generally recognized state of the art at the time it was designed, manufactured, packaged, and labeled. *Bragg v. Hi-Ranger, Inc.*, 462 S.E.2d 321 (S.C. Ct. App. 1995); *Reed v. Tiffin Homes, Inc.*, 697 F.2d 1192 (4th Cir. 1982).

(12) No Defect. Plaintiffs' claims are barred in whole or in part because there was no defect in the prescription drug at issue at the time it left Defendant's possession. *Claytor v. General Motors Corp.*, 286 S.E.2d 129 (S.C. 1982).

(13) Estoppel. Plaintiffs' claims are barred by the doctrine of estoppel. *Cothran v. Brown*, 592 S.E.2d 629, 632 (S.C. 2004); *Ables v. Gladden*, 664 S.E.2d 442, 446 (S.C. 2008); *Provident Life & Accident Ins. Co. v. Driver*, 451 S.E.2d 924, 928-29 (S.C. Ct. App. 1994).

(14) Informed Consent, Release, and Waiver. Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver. *Provident Life & Accident Ins. Co. v. Driver*, 451 S.E.2d 924, 928-29 (S.C. Ct. App. 1994); *see also Faile v. Bycura* 346 S.E.2d 528 (S.C. 1986) (discussing informed consent; if the plaintiff's consent to a treatment was an informed, voluntary choice, plaintiff cannot complain that a disclosed risk occurred).

(15) Peculiar Susceptibility. At all times pertinent to the Complaint, Defendant did not have any knowledge of any peculiar susceptibility of Plaintiffs to damage or injury from mental

anguish, if any. Plaintiffs' Complaint seeks damages for injuries for mental anguish with which a reasonable person, normally constituted, would have been able to cope adequately. *Shipman v. Glenn*, 443 S.E. 2d 921 (S.C. Ct. App. 1994).

(16) Standard of Care. Defendant denies any negligence on its part and shows that, at all times relevant to Plaintiffs' Complaint, it met or exceeded the standard of care. *Bonaparte v. Floyd*, 354 S.E. 2d 40 (S.C. Ct. App. 1987).

(17) Good Faith. Defendant acted reasonably and in good faith at all material times herein, based on all relevant facts known by it at time so acted.

(18) Federal Preemption. Plaintiffs' state law claims are expressly and impliedly preempted by federal law and barred by the doctrine of primary jurisdiction. *See* 21 U.S.C. § 301 to 309, 71 Fed. Reg. 3922 (January 24, 2006).

(19) Benefit Outweighed the Risk. Plaintiffs' claims are barred because the benefits of the product at issue outweighed the risks. *Bragg v. Hi-Ranger, Inc.*, 319 S.C. 531, 462 S.E.2d 321, 328 (Ct. App. 1995) (setting out the two tests that have evolved to determine whether a product is in a defective condition unreasonably dangerous for its intended use, and noting that South Carolina courts balance the utility inherent in the design of the product with the magnitude of the risk to determine the reasonableness of the manufacturer's action in designing the product); *Reed v. Tiffin Motor Homes, Inc.*, 697 F.2d 1192, 1197 (4th Cir. 1982) (setting out test for product liability, including risk-utility doctrine).

(20) Regulatory Compliance. Plaintiffs' claims are further barred in whole or in part by the Defendant's compliance with all applicable statutes and with the applicable requirements and regulations of the Food and Drug Administration.

(21) Foreseeability. Any injury sustained by Plaintiffs is the result of an unforeseeable

series of events over which Lilly had no control, and as such, constitutes an act of God for which Defendant cannot be held accountable. *Montgomery v. Nat'l Convoy & Trucking Co.*, 195 S.E. 247 (S.C. 1938).

(22) Restatement of Torts. Plaintiffs' claims are barred under the Restatement (Second) of Torts §§ 388, Comment n, and 402A, Comments j and k, and any similar doctrines and/or principles in the Restatement (Third) of Torts.

(23) Commercial Speech. The First Amendment of the United States Constitution and similar provisions in applicable state constitutions protect the promotion of products sold or manufactured by Defendant and its subsidiaries and affiliates.

(24) Reliance. Plaintiff's claims are barred, in whole or in part, because Plaintiffs' did no reasonably rely on any act, omission, or representation made by Defendant. *West v. Gladney*, 533 S.E.2d 334 (S.C. Ct. App. 2000).

(25) Consumer Expectations. Plaintiffs' claims are barred because the relevant product was consistent with or exceeded consumer expectations. *Branham v. Ford Motor Co.*, 701 S.E.2d 5 (S.C. 2010).

(26) Idiosyncratic Risk. Plaintiffs cannot recover to the extent any injury, increased risk, or damages resulted from pre-existing conditions, unrelated medical, genetic or idiosyncratic conditions, illnesses, or diseases.

(27) No Express or Implied Warranties. Defendant did not make to Plaintiffs nor breach any express or implied warranties or breach any warranties created by law under South Carolina Commercial Code, S.C. Code Ann. § 36-2-101 et seq.

(28) Unconstitutionality of Punitive Damages. The Complaint fails to state a claim for punitive damages upon which relief can be granted. Any claims asserted for punitive damages

are barred because Defendant has not committed any acts or omissions which would entitle Plaintiffs to recover punitive damages. Any of the claims asserted in the Complaint for punitive damages are further barred because any award of punitive damages would violate Defendant's rights guaranteed by the United States Constitution, the South Carolina Constitution, and applicable case law. Further, an award of punitive damages under South Carolina law violates the Due Process Clauses in the Fifth, Sixth, and Fourteenth Amendments, the Double Jeopardy Clause of the Fifth Amendment, and the Commerce Clause of the United States Constitution and Article I, Section 3 of the South Carolina Constitution. U.S. Const. Amend. 5 & 14; S.C. Const. Art. 1, §3; *State Farm Mutual Auto Ins. Co. v. Campbell*, 538 U.S. 408, 123 S. Ct. 1513 (2003).

(29) Bifurcated Trial for Punitive Damages. A claim for punitive damages against Defendant in this case cannot be sustained because any award of punitive damages under South Carolina law without bifurcating the trial and trying all punitive damage issues only if and after liability on the merits has been found would violate Defendant's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution, and would be improper under the common law and public policy of South Carolina. S.C. Code Ann. § 15-32-520.

(30) Limit of Punitive Damages Award. Any claim for punitive damages against Defendant in this case cannot be sustained because any award of punitive damages under South Carolina law subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury would impose would violate Defendant's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due process provisions of the South Carolina Constitution, and would be improper under the common law and public policy of South Carolina. S.C. Code Ann. § 15-32-530.

(31) Punitive Damages Based on Strict Liability or Breach of Warranty. The claims asserted in the Complaint for punitive damages based on strict liability or breach of warranty are barred because South Carolina forbids the award of such damages. *Barnwell v. Barber-Coleman Co.*, 393 S.E. 2d 162 (S.C. 1989).

(32) Punitive Damages – Protections and Limitations. Defendant is entitled to the protections and limitations afforded under S.C. Code Ann. § 15-32-510, et seq.

(33) Economic Loss. Plaintiff's claims are barred, in whole or in part, by the economic loss doctrine. *Sapp v. Ford Motor Co.* 687 S.E.2d 47 (S.C. 2009).

(34) Fraud. Plaintiffs' claims of fraud are barred by reason of the Complaint's failure to allege the factual circumstances constituting the alleged fraud with particularity. Fed. R. Civ. P. 9(b); *Chewning v. Ford Motor Co.*, 550 S.E.2d 584 (S.C. Ct. App. 2001).

(35) Plaintiffs' claims are barred in whole or in part because adverse events associated with the discontinuation of Cymbalta® in clinical trials are appropriately described in the Cymbalta® prescribing materials. *Phelan v. Synthes (U.S.A.)*, 35 F. App'x 102 (4th Cir. 2002).

(36) Reservation. Due to the complexity of issues involved in this case, the Defendant has set forth many defenses in its Answer, which it incorporates by reference, and reserves the right to supplement this response with further authorities in support of those defenses and to assert other defenses based on facts revealed during discovery and its ongoing investigation of the claims.

(5) Absent special instructions from the assigned judge, the parties shall propose dates for the following deadlines listed in Local Civil rule 16.02:

a. Exchange of Fed. R. Civ. P. 26(a)(2) expert disclosures; and

b. Completion of discovery

RESPONSE: The Court has entered a scheduling order setting the deadline for the exchange of expert disclosures and completion of discovery; however, the Parties wish to propose alternate dates. The Parties agree on a schedule for this case but differ in the particulars outlined above concerning discovery.

(6) The parties shall inform the Court whether there are any special circumstances which would affect the time frames applied in preparing the scheduling order. See generally Local Civil Rule 16.02(C) (Content of Scheduling Order).

RESPONSE: At this time, the Parties are not aware of any issues responsive to this interrogatory.

(7) The parties shall provide any additional information requested in the Pre-Scheduling Order (Local Civil Rule 16.01) or otherwise requested by the assigned judge.

ANSWER: The Court requested the Parties consider whether they wish to consent to trial before a United States Magistrate Judge. The Parties do not consent to trial before a United States Magistrate Judge.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2013, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

s/James F. Rogers
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